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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/613,220   | 07/02/2003  | H. Garrett Wada      | 100/07211           | 7051             |
| 21569  | 7590        | 10/06/2005           | EXAMINER            |                  |
| CALIPER LIFE SCIENCES, INC.<br>605 FAIRCHILD DRIVE<br>MOUNTAIN VIEW, CA 94043-2234 |             |                      | DAVIS, DEBORAH A    |                  |
|  |             | ART UNIT             | PAPER NUMBER        | 1641             |

DATE MAILED: 10/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                              |                     |  |
|------------------------------|------------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b>       | <b>Applicant(s)</b> |  |
|                              | 10/613,220                   | WADA ET AL.         |  |
|                              | Examiner<br>Deborah A. Davis | Art Unit<br>1641    |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 27 June 2005.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-23 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|  | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 27, 2005 has been entered.

### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson et al (USP#6,007,690) in view of Spence et al (USP#6,540,895).

The claims are broadly drawn to a microfluidic system for detection a component of interest in a sample. Nelson et al teaches a microfluidic devices comprising several alternative embodiments (abstract). In one embodiment, Nelson teaches a microfluidic device that comprise of a first channel and a second channel (figure 18). The first channel has an electrophoretic flowpaths, which examiner interprets as a gel separation region (figure 18, #236) and the region can have on to a plurality of affinity zones, which

examiner interprets as the binding regions (column 18, lines 28-32). Nelson et al teaches that the gel is a polyacrylamide (column 11, lines 47). Sample components can be captured by the affinity media in the affinity zones, which satisfies the limitation of step (d) of a component-binding moiety fluidly coupled to the binding region (column 17, lines 63-67). The affinity zones are provided with detectors configured to detect fluorescence or electrochimilluminescence from components of interests (column 17, lines 27-31). The binding moieties can comprise of a range of reagents as in lectins, antibodies, biotin binding groups and a variety of proteins (column 17, lines 34-40). The second channel comprise of detection regions (figure 18, #278) and according to the reference, the first channel can also comprise of a detection region for detecting a first analyte (column 10, lines 18-22). The detection regions comprise of detectors and therefore appear to be configured proximal toe the first and second detection regions. Enrichment zones can be positioned in the first and the second channels, which is interpreted as a particle-stacking region (figure 19, #280). According to Nelson, the enrichment channel can employ paramagnetic beads that are coated with affinity medium and can be retained in the channel (column 6, lines 25-29 and column 21, lines 14-23). The beads utilized can also be made of alternative materials as in porous glass and polymeric (column 5, lines 60-63). Nelson discloses several embodiments that include alternative fluid direction systems as a means to transport fluid through the first and second microchannels. One example employs a pumping means for moving a sample through the channel system (column 6, lines 61-62), wherein this pumping means can be interpreted as a pressure based fluid system. The fluid direction system

can also be controlled by electrokinetic transport (column 23, lines 10-17). Nelson et al teaches a variety of configurations that can comprise of affinity zones (binding regions). In figure 19, a third channel, downstream of the first two channels comprises electrophoretic flowpaths that can comprise of affinity zones for binding of an analyte.

The device of Nelson et al does not particularly point out a control system linked to the fluid direction system configured to instruct sample transport.

However, the reference of Spence et al teaches cell sorting utilizing microfluidic systems controlled by a computer or microprocessor that control fluid flow. Different algorithms for sorting in the microfluidic device can be implemented by different computer programs (column 15, lines 6-27).

It would have been obvious to one of ordinary skill in the art to modify the teachings of Nelson et al to include a control system to instruct fluid direction as taught by Spence et al because procedures can be programmed using any suitable software that can perform a variety of functions (column 15, lines 5-27). Further, it is well known in the art to utilize these control systems with microfluidic device systems.

### ***Conclusion***

4. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah A. Davis whose telephone number is (571) 272-0818. The examiner can normally be reached on 8-5 Monday thru Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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September 23, 2004



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